USSN 09/041,994

Art Unit: 1646

In the Claims:

Please cancel without prejudice or disclaimer claims 4, 7, 11, 43 and 45-48.

- 2 -

Please amend claims 1, 10, 42 and 44, as follows:

- 1. (Twice Amended) An isolated nucleic acid molecule which encodes a RAC3 protein, comprising a nucleotide sequence at least 90% identical to the nucleotide sequence of SEQ ID NO:1, wherein said RAC3 protein interacts with and activates an AF-2 domain-containing steroid/nuclear receptor.
- 10. (Twice Amended) An isolated nucleic acid molecule encoding a RAC3 protein comprising a nucleotide sequence which hybridizes under hybridization conditions of hybridization in 50% formamide at 42°C followed by washing in 1XSSC/0.1%SDS at 65°C to a nucleic acid molecule which is the complementary sequence of SEQ ID NO:1, wherein said RAC3 protein interacts with and activates an AF-2 domain-containing steroid/nuclear receptor.
- 42. (Amended) An isolated nucleic acid molecule at least 200 nucleotides in length which encodes a RAC3 N-terminal steroid receptor interacting domain comprising amino acids 613 to 752 of SEQ ID NO:2.
- 44. (Amended) An isolated nucleic acid molecule at least 200 nucleotides in length which encodes a RAC3 C-terminal transactivating domain comprising amino acids 1017 to 1179 of SEQ ID NO:2.

REMARKS

Applicants greatly appreciate the comments provided in an interview between Examiner Pak and Applicants' representatives Elizabeth Hanley and Debra Milasincic on February 27, 2001. The instant Amendment incorporates the suggestions made by the Examiner.

The specification has also been amended at page 14 to incorporate text from the specification of the priority provisional application no. 60/073,674 filed February 4, 1998. The content of the provisional application was incorporated by reference into the instant

application as indicated on page 1, lines 3-4. Pursuant to M.P.E.P. §608.01(p), Applicants declare that the text added by amendment to page 14 is the same as the material appearing at page 11 of the priority application. No new matter has been added.

Claims 1, 2, 4, 5, 7-11, 14-18, and 42-48 were pending in the instant application.

Claims 4, 7, 11, 43, 45 and 46-48 have been canceled without prejudice. Claims 1, 10, 42 and 44 have been amended. No new claims have been added. Accordingly, claims 1, 2, 5, 9-10, 14-18, 42 and 44 will be pending upon entry of the instant amendment. Attached hereto is Appendix A, captioned "VERSION WITH MARKINGS TO SHOW

CHANGES MADE" including a marked-up version of the changes made to the claims by current amendment. Cancellation and amendment of claims should in no way be construed as an acquiescence to any of the rejections of record. Applicants reserve the right to pursue the claims as originally filed in this or one or more separate applications.

Objection to the Specification

The specification has been objected to as failing to provide proper antecedent basis for certain claimed subject matter. In particular, the Examiner indicates that claims 10-11 and 42-48 "are directed to the limitations of 'specific hybridization conditions' which are not disclosed in the specification".

The specification has been amended at page 14 to include specific hybridization conditions. Support for the amendment to the specification can be found in the priority application at least, for example, at page 11. Upon entry of this amendment, Applicants submit that recitation of specific hybridization conditions in the pending claims will be fully supported.

Information Disclosure Statement

The Examiner asserts that "[t]he information disclosure statement filed 10 February 1999 (Paper No. 6) fails in part to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. In particular, the Examiner has considered references BR-BS "to the extent possible" in view of the fact that the references do not have a date in the form 1449.

References AE-BP have been considered "to the extent possible" with the date listed on the 1449 having been considered the date "relevant for the submission of IDS". Furthermore, the Examiner states that references AE-BP do not fully comply with provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the references "are sequences which are not in English language and require an explanation of the relevance to the claims in the application."

Applicants appreciate the Examiner's willingness to consider the references to the extent possible, given the unique nature of the references, i.e., GenBank records and BLAST search results. Applicants respectfully submit that references AE-BP are in the English language as the references contain sequence information listed according to standard genetic code, which is universally recited in characters of the English alphabet. Moreover, all other fields of data represented in the references, e.g., authors, titles, annotations, etc. are clearly in the English language. As the referenced AE-BP are in the English language and have been considered "to the extent possible", Applicants submit that the IDS previously submitted suffices to bring the Examiner's attention to the information of which they and their attorney are aware. Should the Examiner require a supplemental Information Disclosure Statement upon consideration of the instant response, the Examiner is urged to call Applicants' attorney at (617) 227-7400.

Claim Rejections - 35 USC § 112

Claims 42, 44, and 45 stand rejected under 35 U.S.C. 112, first paragraph, as "containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention". In particular, the Office Action states that claims 44 and 45 "encompass a species limitation of an amino acid '1018' which is new matter". Applicants traverse.

Claim 45 has been cancelled. Claim 42 does not recite an amino acid "1018". Claim 44 has been amended to recite an amino acid "1017" as the N-terminal amino acid of the claimed C-terminal transactivating domain. The amendment is supported in the instant specification at least, for example, at page 5, lines 16-17; at page 8, lines 28-31; and at page 9, lines 3-4. Applicants respectfully request reconsideration and withdrawal of the

rejection.

Claims 8 and 42-45 stand rejected under 35 U.S.C. 112, second paragraph, as "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention". In particular, the claims stand rejected over the recitation "of the term 'substantially identical' which is ambiguous because it is not clear what is the metes and bounds of the term". Applicants traverse.

It is Applicants position that one skilled in the art would readily understand the meaning of the term "substantially identical" as recited in the claims, in particular, in view of Applicants' definition of the term recited in the specification at amended page 9. However, in order to expedite an allowance of the instant application, claims 8, 43 and 45 have been cancelled and claims 42 and 44 have been amended to no longer recite the language "substantially identical". Applicants respectfully submit that the cancellation of claims 8, 43 and 45 and amendment of claims 42 and 44 obviates the rejection and, accordingly, request reconsideration and withdrawal of the rejection.

Claim Rejections - 35 USC § 102 and § 103

Claims 1, 4, 7-8, 10-11, and 42-48 stand rejected under 35 U.S.C. 102(a) as being anticipated by Anzick *et al.* ((AA); Science, 1997) and for reasons set forth in the previous office action and further stand rejected under 35 U.S.C. 103(a) as being unpatentable over Anzick et al ((AA); Science, 1997) in view of Li *et al.* ((AC); PNAS, 1997) and Hardy *et al.* ((U); J. Clin. Endocrinol. Metabol., 1996). The Examiner relies on the teachings of Anzick *et al.*, Li *et al.* and Hardy *et al.* for reasons of record. Applicants traverse the rejections.

Applicants submit herewith an executed Rule 1.131 declaration (discussed in detail in the previous Amendment and Response) which antedates the Anzick *et al.* reference. The declaration evidences that the present invention was reduced to practice by the instant inventors prior to the effective date of the Anzick *et al.* reference. The declaration includes Appendix A which was inadvertantly ommited from the declaration filed April 14, 2000 (noted in the Advisory Action mailed January 10, 2001). In view of the Rule 1.131

declaration, Applicants submit that the Anzick *et al.* reference is not available as prior art against the present invention under 35 U.S.C. §102(a). Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. 102(a) as anticipated by Anzick *et al.*

Applicants also submit herewith an executed declaration pursuant to 37 CFR §1.132 which indicates that Paulo J. Gomes, who is a co-author with inventors J. Don Chen and Hui Li of the Li *et al.* reference, is *not* a co-inventor of the subject matter described and claimed in the instant patent application. As indicated in the declaration, Paulo J. Gomes provided only technical assistance to Drs. J. Don Chen and Hui Li in performing the work described in the Li *et al.* reference. Accordingly, the Li *et al.* reference represents Applicants' own work, published within one year of the filing of the present application, and cannot be used against Applicants under 35 U.S.C.§ 103(a). *In re Katz*, 687 F.2d 450, 215 USPQ 14 (CCPA 1958). The enclosed Rule 1.132 declaration corrects the date of publication of the Li *et al.* reference cited in paragraph 2 (error pointed out in the Advisory Action dated January 24, 2001 and discussed in the interview held February 28, 2001).

As the Anzick *et al.* reference and the Li *et al.* reference are unavailable as prior art references, only the Hardy *et al.* reference remains as the basis for the outstanding § 103 rejection. Applicants respectfully submit that in view of the declarations pursuant 37 CFR §§1.131 and 1.132, the aforementioned rejection is rendered moot. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

SUMMARY

Applicants submit that all pending claims are presently in condition for allowance. If a telephone conversation with Applicants' attorney would expedite allowance of the above-identified application, the Examiner is urged to call Applicants' attorney at (617) 227-7400.

Date: March 29, 2001

LAHIVE & COCKFIELD, LLP

Attorneys at Law

Debra J. Milasincic

Reg. No. 46,931 28 State Street

Boston, MA 02109

(617) 227-7400

(617) 742-4214

Enclosures (executed Rule 131 and 132 Declarations)

APPENDIX A VERSION WITH MARKINGS TO SHOW CHANGES MADE

- 1. (Twice Amended) An isolated nucleic acid molecule which encodes a RAC3 protein, comprising a nucleotide sequence at least [80%] 90% identical to the nucleotide sequence of SEQ ID NO:1, wherein said RAC3 protein interacts with and activates an AF-2 domain-containing steroid/nuclear receptor.
- 10. (Twice Amended) An isolated nucleic acid molecule encoding a RAC3 protein comprising a nucleotide sequence which hybridizes under hybridization conditions of hybridization in 50% formamide at 42°C followed by washing in 1XSSC/0.1%SDS at 65°C to a nucleic acid molecule which is the complementary sequence of SEQ ID NO:1, wherein said RAC3 protein interacts with and activates an AF-2 domain-containing steroid/nuclear receptor.
- 42. (Amended) An isolated nucleic acid molecule at least 200 nucleotides in length which encodes a RAC3 [protein comprising an] N-terminal steroid receptor interacting domain [which is substantially identical to] comprising amino acids 613 to 752 of SEQ ID NO:2[, wherein said nucleic acid molecule hybridizes under hybridization conditions of hybridization in 50% formamide at 42°C followed by washing in 1XSSC/0.1%SDS at 65°C to a nucleic acid molecule which is the complementary sequence of SEQ ID NO:1].
- 44. (Amended) An isolated nucleic acid molecule at least 200 nucleotides in length which encodes a RAC3 [protein comprising a] C-terminal transactivating domain [which is substantially identical to] comprising amino acids [1018] 1017 to 1179 of SEQ ID NO:2[, wherein said nucleic acid molecule hybridizes under hybridization conditions of hybridization in 50% formamide at 42°C followed by washing in 1XSSC/0.1%SDS at 65°C to a nucleic acid molecule which is the complementary sequence of SEQ ID NO:1].